510(k) SUMMARY

FEB 2 4 2004

AcuNav 90/10 Diagnostic Ultrasound Catheter

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. **Submitted by:**

Siemens Medical Solutions USA, Inc., Ultrasound Division
1230 Shorebird Way
Mountain View, CA 94039

Contact Person:
Iskra Mraković
Manager, Regulatory Affairs

Phone: (650) 694-5004
Fax: (650) 961-6168

2. **Proprietary Name:**
AcuNav 90/10 Diagnostic Ultrasound Catheter

Common/Usual Name:
Intracardiac/Intravascular Ultrasound Catheter.

Classification Name:
Regulatory Class: II
Review Category: Tier II

	FR Number	Product Code
Diagnostic Intravascular Catheter	870.1200	74-DQO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3. **Predicate Device:**
ACUSON AcuNav® 90/10 Diagnostic Ultrasound Catheter

4. **Device Description:**

As described in the previously cleared 510(k) submissions, (K992631 on December 15, 1999, and K010950 on June 27, 2001), the AcuNav catheter is comprised of a single-use, disposable ultrasonic phased-array imaging transducer and a catheter which is 10 Fr (3.33 mm) in diameter and 90 cm in insertable length. The device is capable of imaging at multiple frequencies and obtaining blood flow data in multiple ultrasound modes. The distal portion of the catheter can be deflected in four directions in two orthogonal planes: left-right (in a plane perpendicular to the image plane) and anterior-posterior (in a

plane coincident with the image plane). The range of deflection is 160° in each direction. The AcuNav catheter is comprised of three major components: (1) the catheter itself; (2) the steering mechanism; and (3) the reusable system cable.

The AcuNav 90/10 Diagnostic Ultrasound Catheter has been designed to meet the following product safety standards [as required by 21 CFR § 807.87(j)].

- UL 2601-1, Safety Requirements for Medical Equipment
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- CISPR 11, Class A
- IEC 601-1-1
- IEC 601-1-2
- ISO 10993 Biocompatibility

5. Intended Use:

The AcuNav catheter is intended for use in the visualization of vascular anatomy and physiology, cardiac and great vessel anatomy and physiology, visualization of other devices in the heart or vasculature, as well as measurements of blood flow, cardiac and vascular anatomic dimensions.

6. Technological Comparison to Predicate Device:

The AcuNav 90/10 Diagnostic Ultrasound Catheter is substantially equivalent to the ACUSON AcuNav® 90/10 Diagnostic Ultrasound Catheter (K992631, 11/8/2001).

Both catheters are ultrasound-tipped catheter devices used directly within the vasculature and/or the heart for intravascular or intracardiac ultrasound imaging. Devices are specifically indicated for use in visualization of vascular anatomy, cardiac and great vessel anatomy and physiology, or other devices in the heart, as well as measurement of blood flow.

End of 510(k) Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 4 2007

Siemens Medical Solutions USA, Inc.
c/o Dr. Iskra Mrakovic
Regulatory Affairs Manager
1230 Shorebird Way
P.O. Box 7393
Mountain View, CA 94043

Re: K033650
Trade/Device Name: Acunav 90/10 Diagnostic Ultrasound Catheter
Regulation Number: 21 CFR 870.1200 and 892.1570
Regulation Name: Diagnostic Intravascular Catheter and
Diagnostic Ultrasound Transducer
Regulatory Class: II
Product Code: OBJ and ITX
Dated: November 19, 2003
Received: November 20, 2003

Dear Dr. Mrakovic:

This letter corrects our substantially equivalent letter of February 24, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

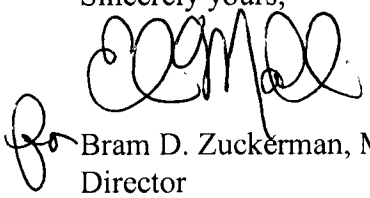
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-4008. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Diagnostic Ultrasound Indications for Use Form
Aspen Diagnostic Ultrasound System

510(k) Number: K033650

Device Name: AcuNav 90/10 (IC10V5) Diagnostic Ultrasound Catheter

Indications for Use: The AcuNav™ Diagnostic Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart.

Ultrasound System: Aspen

Transducer: AcuNav

	Mode of Operation									
Clinical Application	**A**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Color Velocity Imaging**	**Combined (Specify)**	**Other: Harmonic Imaging**
Ophtalmic										
Fetal										
Abdominal										
Intraoperative (Vascular)										
Intraoperative (Neurological)										
Pediatric										
Small Organ (Specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal		P	P	P	P	P	P		P*	P
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Intra-Cardiac)		P	P	P	P	P	P		P*	P

P=Previously cleared by the FDA under premarket notification K992631.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Donna R. Lochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033650

Diagnostic Ultrasound Indications for Use Form
Cypress Diagnostic Ultrasound System

510(k) Number: K033650

Device Name: AcuNav 90/10 (IC10V5) Diagnostic Ultrasound Catheter

Indications for Use: The AcuNav™ Diagnostic Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart.

Ultrasound System: Cypress

Transducer: AcuNav

	Mode of Operation									
Clinical Application	**A**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Color Velocity Imaging**	**Combined (Specify)**	**Other: Harmonic Imaging**
Ophtalmic										
Fetal										
Abdominal										
Intraoperative (Vascular)										
Intraoperative (Neurological)										
Pediatric										
Small Organ (Specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P			P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal		P	P	P	P	P			P*	P
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Intra-Cardiac)		P	P	P	P	P			P*	P

P=Previously cleared by the FDA under premarket notification K992631.

Additional Comments:

*The Cypress Ultrasound System does not provide combined modes where more than one scanning mode is active simultaneously.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Donna R. Vochmel

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033650

Diagnostic Ultrasound Indications for Use Form
Sequoia Diagnostic Ultrasound System

510(k) Number: K033650

Device Name: AcuNav 90/10 (IC10V5) Diagnostic Ultrasound Catheter

Indications for Use: The AcuNav™ Diagnostic Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart.

Ultrasound System: Sequoia

Transducer: AcuNav

	Mode of Operation									
Clinical Application	**A**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Color Velocity Imaging**	**Combined (Specify)**	**Other: Harmonic Imaging**
Ophtalmic										
Fetal										
Abdominal										
Intraoperative (Vascular)										
Intraoperative (Neurological)										
Pediatric										
Small Organ (Specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal		P	P	P	P	P	P		P*	P
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Intra-Cardiac)		P	P	P	P	P	P		P*	P

P=Previously cleared by the FDA under premarket notification K992631.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Donna R. Kochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033650